

REMARKS

Claims 1-66 were examined. The claims have been amended as noted above. Reexamination and reconsideration of the claims as amended are respectfully requested.

Applicants thank Examiner Kearney for the courteous and helpful interview held on August 21, 2002.

Claims 20, 22, 24-26 and 28 have been amended to properly recite multiple dependency in the alternative form. Applicants believe that claims 20-32 are now in proper form for examination.

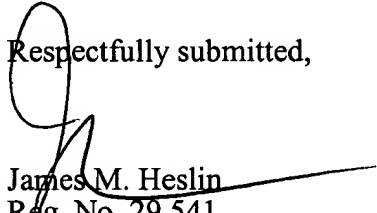
Dependent claims 1, 33, and 51 have been amended so that all dependent claims recite that the deployed electrode structures face each other. As agreed at the recent interview, such amendments overcome the art rejections.

Attached is a marked-up version of the changes made by the current amendment. The attached page is captioned with "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

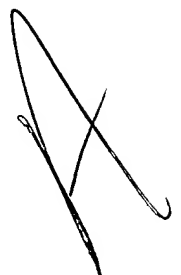
Applicants believe that all claims are now in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,


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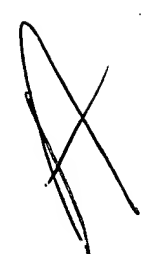
VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A probe for deploying electrode arrays, said probe comprising:
a shaft having a distal end and a proximal end;
a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face; and
a second array of electrodes mounted on the shaft at a location spaced-apart proximally from first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face;
wherein **[concave faces are opposed to each other]** the concave face of the first array faces the concave face of the second array when the arrays are deployed.

~~16.~~ A method for treating a treatment region in tissue, said method comprising:
deploying a first array of electrodes in tissue on one side of the treatment region, wherein said first electrode array has a concave face;
deploying a second array of electrodes in tissue along an axis with the first array on another side of the treatment region, wherein said second electrode array has a concave face and wherein the concave face of the first electrode array faces the concave face of the second electrode array when said arrays are deployed; and
applying electrical current between the first and second electrode arrays.

~~20.~~ (Amended) A method as in any of claims 16-18 or 19, wherein the tissue is selected from the group consisting of liver, lung, kidney, pancreas, stomach, uterus, and spleen.

~~22.~~ (Amended) A method as in any of claims 16-18 or 19, wherein electrical current is applied at a frequency in the range from 300 kHz to 1.2 MHz.



24. (Amended) A method as in any of claims 16-18 or 19, wherein applying electrical current comprises coupling one pole of a radiofrequency power supply to the first electrode array and another pole of the radiofrequency power supply to the second electrode array and energizing the power supply.

~~25~~ (Amended) A method as in any of claims ~~16-18 or 19~~, wherein the first and second electrode arrays each span a planar area in the range between 3 cm² to 20 cm², and wherein the first and second arrays are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

~~26~~ (Amended) A method as in any of claims ~~16-18 or 19~~, wherein the tissue volume between the first electrode array and the second electrode is in the range from 30 cm³ to 150 cm³.


~~28~~ (Amended) A method as in any of claims ~~16-18 or 19~~, wherein said first electrode array includes a first axial conductor extending at least part of the way to the second array along the axis therebetween.

~~33~~ (Amended) A method for bipolar radiofrequency necrosis of tissue, said method comprising:

deploying a first array of electrodes in tissue on one side of a treatment region, wherein said first array has a concave [transverse] face and an axial conductor extending in an axial direction from the concave [transverse] face;

deploying a second array of electrodes in tissue on another side of the treatment region, wherein said second array has a concave [transverse] face and an axial conductor extending in an axial direction opposed to the axial conductor on the first electrode array and wherein the concave face of the first array faces the concave face of the second array when the arrays are disposed; and

applying bipolar radiofrequency current to the tissue between the first and second electrode arrays.



~~51.~~ (Amended) A probe for deploying electrode arrays, said probe comprising:

- a shaft having a distal end and a proximal end;
- a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face; and
- a second array of electrodes mounted on the shaft at a location spaced-apart proximally from the first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face;

wherein the first array is electrically isolated from the second array to permit the arrays to be connected to a power supply for bipolar operation and wherein the concave face of the first array faces the concave face of the second array when the arrays are deployed.

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APPENDIX A
COMPLETE SET OF PENDING CLAIMS

Sub B17
1. (Amended) A probe for deploying electrode arrays, said probe comprising:
a shaft having a distal end and a proximal end;
a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face; and
a second array of electrodes mounted on the shaft at a location spaced-apart proximally from first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face;
wherein the concave face of the first array faces the concave face of the second array when the arrays are deployed.

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2. (As filed) A probe as in claim 1, wherein the first and second electrode arrays each comprise a plurality of individual electrodes which initially move axially and then evert as they are deployed.

3. (As filed) A probe as in claim 1, wherein the shaft has a self-penetrating tip.

4. (As filed) A probe as in claim 1 or 3, wherein the shaft has at least once cavity for receiving the first and second electrode arrays when retracted.

5. (As filed) A probe as in claim 1 or 3, wherein the shaft has at least one cavity for receiving the first electrode array when retracted and at least a second cavity for receiving the second electrode array when retracted.

6. (As filed) A probe as in claim 1 or 3, further comprising:

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a first rod connected to the first electrode array and slidably disposed in the shaft, wherein distal advancement of the first rod relative to the shaft causes the first electrode array to deploy distally;

a second rod connected to the second electrode array and slidably disposed in the shaft, wherein proximal retraction of the second rod relative to the shaft causes the second electrode array to deploy proximally.

Al 7. (As filed) A probe as in claim 1 or 3, wherein the first electrode array spans a planar area in the range between 3 cm^2 to 20 cm^2 when deployed, the second electrode array spans a planar area in the range between 3 cm^2 and 20 cm^2 when deployed, and the first and second areas are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

8. (As filed) A probe as in claim 1 or 3, wherein the volume between the first electrode array when deployed and the second electrode when deployed is in the range from 30 cm^3 to 150 cm^3 .

9. (As filed) A probe as in claim 8, wherein the volume is in the range from 50 cm^3 to 70 cm^3 .

10. (As filed) A probe as in claim 1 or 3, wherein the first electrode array and second electrode array are electrically isolated from each other, further comprising a first connector for connecting the first electrode array to one pole of a power supply and a second connector for connecting the second array to a second pole of a power supply.

Sub B27 11. (As filed) A probe as in claim 10, further comprising a first axial conductor extending proximally along the shaft from the first electrode array to a location distal to the second electrode array, said first axial conductor being electrically coupled to the first electrode array.

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~~12~~¹¹ (As filed) A probe as in claim ~~N~~¹⁰, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.

~~13~~¹² (As filed) A probe as in claim ~~N~~¹⁰, further comprising a second axial conductor extending distally along the shaft from the second electrode array to a location proximal to the first axial conductor so that a gap exists between the first and second axial conductors, said second axial conductor being electrically coupled to the second electrode array.

~~14~~¹³ (As filed) A probe as in claim ~~13~~¹², wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial conductor lies closer to the first electrode array than does any portion of the second electrode array.

~~15~~¹⁴ (As filed) A probe as in claim ~~13~~¹², wherein the distance between the inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

~~16~~¹⁵ (Amended) A method for treating a treatment region in tissue, said method comprising:

deploying a first array of electrodes in tissue on one side of the treatment region, wherein said first electrode array has a concave face;

deploying a second array of electrodes in tissue along an axis with the first array on another side of the treatment region, wherein said second electrode array has a concave face and wherein the concave face of the first electrode array faces the concave face of the second electrode array when said arrays are deployed; and

applying electrical current between the first and second electrode arrays.

~~17~~¹⁶ (As filed) A method as in claim ~~16~~¹⁵, wherein deploying the first electrode array comprises introducing a first probe through tissue to a location on one side of the treatment

region and advancing a first plurality of at least three electrodes from the probe in an everting pattern.

~~17~~ 18. (As filed) A method as in claim ~~17~~ 14, wherein deploying the second electrode array comprises advancing a second plurality of at least three electrodes from the probe in an everting pattern at a location on the other side of the treatment region.

~~18~~ 19. (As filed) A method as in claim ~~17~~ 14, wherein deploying the second electrode array comprises introducing a second probe through tissue to a location on the other side of the treatment region and advancing a plurality of at least three electrodes in an everting pattern.

A1 ~~19~~ 20. (Amended) A method as in any of claims 16-18 or 19, wherein the tissue is selected from the group consisting of liver, lung, kidney, pancreas, stomach, uterus, and spleen.

~~20~~ 21. (As filed) A method as in claim ~~20~~ 19, wherein the treatment region is a tumor.

~~21~~ 22. (Amended) A method as in any of claims ~~16-18~~ 15, 17, 18 or 19, wherein electrical current is applied at a frequency in the range from 300 kHz to 1.2 MHz.

~~22~~ 23. A method as in claim ~~22~~ 21, wherein electrical current is applied at a power in the range from 50W to 300W.

[~~24~~ 24. (Amended) A method as in any of claims ~~16-18~~ 15, 17, 18 or 19, wherein applying electrical current comprises coupling one pole of a radiofrequency power supply to the first electrode array and another pole of the radiofrequency power supply to the second electrode array and energizing the power supply.

~~25~~ 25. (Amended) A method as in any of claims ~~16-18~~ 15, 17, 18 or 19, wherein the first and second electrode arrays each span a planar area in the range between 3 cm² to 20 cm², and

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wherein the first and second arrays are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

~~26~~²⁴ (Amended) A method as in any of claims ~~16-18~~^{16 17 18} or ~~19~~¹⁸, wherein the tissue volume between the first electrode array and the second electrode is in the range from 30 cm³ to 150 cm³.

~~27~~²⁵ (As filed) A method as in claim ~~26~~²⁴, wherein the volume is in the range from 50 cm³ to 70 cm³.

~~28~~²⁴ (Amended) A method as in any of claims ~~16-18~~^{16 17 18} or ~~19~~¹⁸, wherein said first electrode array includes a first axial conductor extending at least part of the way to the second array along the axis therebetween.

~~29~~²⁷ (As filed) A method as in claim ~~28~~²⁶, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.

~~30~~²⁸ (As filed) A method as in claim ~~28~~²⁶, wherein said second electrode array includes a second axial conductor extending part of the way to the first array along the axis therebetween and wherein there is a gap between termini of the first axial conductor and the second axial conductor.

~~31~~²⁹ (As filed) A method as in claim ~~30~~²⁸, wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial conductor lies closer to the first electrode array than does any portion of the second electrode array.

~~32~~³⁰ (As filed) A method as in claim ~~31~~²⁹, wherein the distance between inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

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31 ~~33~~ (Amended) A method for bipolar radiofrequency necrosis of tissue, said method comprising:

deploying a first array of electrodes in tissue on one side of a treatment region, wherein said first array has a concave face and an axial conductor extending in an axial direction from the concave face;

deploying a second array of electrodes in tissue on another side of the treatment region, wherein said second array has a concave face and an axial conductor extending in an axial direction opposed to the axial conductor on the first electrode array and wherein the concave face of the first array faces the concave face of the second array when the arrays are disposed, and

A1 applying bipolar radiofrequency current to the tissue between the first and second electrode arrays.

~~33~~ 32 (As filed) A method as in claim ~~33~~ wherein deploying the transverse face of the first electrode array comprises introducing a first probe through tissue to a location on one side of the treatment region and advancing a first plurality of at least three electrodes from the probe in a radially diverging pattern.

~~35~~ 33 (As filed) A method as in claim ~~34~~ wherein the diverging pattern is everting.

~~36~~ 34 (As filed) A method as in claim ~~34~~ or ~~35~~ wherein deploying the transverse second electrode array comprises advancing a second plurality of at least three electrodes from the probe in a radially diverging pattern at a location on the other side of the treatment region.

~~37~~ 36 (As filed) A method as in claim ~~36~~ wherein the diverging pattern is everting.

~~38~~ 36 (As filed) A method as in claim ~~34~~ or ~~35~~ wherein deploying the transverse face of the second electrode array comprises introducing a second probe through

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tissue to a location on the other side of the treatment region and advancing a plurality of at least three electrodes in a radially diverging pattern.

~~39~~³⁷ (As filed) A method as in claim ~~38~~³⁶, wherein the diverging pattern is everting.

~~40~~³⁸ (As filed) A method as in claims ~~33, 34, or 35~~^{33, 34, or 35}, wherein the tissue is selected from the group consisting of liver, lung, kidney, pancreas, stomach, uterus, and spleen.

~~41~~³⁹ (As filed) A method as in claim ~~40~~³⁸, wherein the treatment region comprises a tumor lesion.

~~42~~⁴⁰ (As filed) A method as in claims ~~33, 34, or 35~~^{33, 34, or 35}, wherein the bipolar radiofrequency current is applied at a frequency in the range from 300 kHz to 1.2 MHz.

~~43~~⁴¹ (As filed) A method as in claim ~~42~~⁴⁰, wherein the bipolar radiofrequency current is applied at a power in the range from 50W to 300W.

~~44~~⁴² (As filed) A method as in claims ~~33, 34, or 35~~^{33, 34, or 35}, wherein applying the bipolar radiofrequency current comprises coupling one pole of a radiofrequency power supply to the first electrode array and another pole of the radiofrequency power supply to the second electrode array and energizing the power supply.

~~45~~⁴³ (As filed) A method as in claims ~~33, 34, or 35~~^{33, 34, or 35}, wherein the transverse face of the first electrode array spans a planar area in the range between 3 cm² to 20 cm², the transverse face of the second electrode array spans a planar area in the range between 3 cm² and 20 cm², and the first and second arrays are spaced-apart along an axial line between their respective centers by a distance in the range between 2 cm and 10 cm.

~~46~~⁴⁴ (As filed) A method as in claim ~~45~~⁴³, wherein the termini of axial conductors of the first and second electrode arrays are spaced-apart in the axial direction by a distance in the range between 0.5 cm and 5 cm.

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~~47~~^{47.5} (As filed) A method as in claim ~~33~~³³, wherein the tissue volume between the transverse face of the electrode array and the transverse face of the second electrode is in the range from 30 cm³ to 150 cm³.

~~48~~⁴⁸ (As filed) A method as in claim ~~33~~³³, wherein the distance between the termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

~~49~~^{49.1} (As filed) A kit for treating a treatment region in tissue, said kit comprising:

- a first array of electrodes which are deployable in tissue;
- a second array of electrodes which are deployable in tissue; and
- instructions for use setting forth a method according to claim ~~18~~¹⁸ or ~~33~~³³.

~~50~~⁵⁰ (As filed) A kit as in claim ~~41~~⁴¹, further comprising a package for holding the first electrode array, the second electrode array, and the instruction for use.

~~51~~^{51.49} (Amended) A probe for deploying electrode arrays, said probe comprising:

- a shaft having a distal end and a proximal end;
 - a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face; and
 - a second array of electrodes mounted on the shaft at a location spaced-apart proximally from the first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face;
- wherein the first array is electrically isolated from the second array to permit the arrays to be connected to a power supply for bipolar operation and wherein the concave face of the first array faces the concave face of the second array when the arrays are deployed.

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~~52~~⁵⁰ (As filed) A probe as in claim ~~51~~⁴⁸, wherein the first and second electrode arrays each comprise a plurality of individual electrodes which initially move axially and then evert as they are deployed.

~~53~~⁵¹ (As filed) A probe as in claim ~~51~~⁴⁸, wherein the shaft has a self-penetrating tip.

~~54~~⁵² (As filed) A probe as in claim ~~51~~⁴⁸ or ~~53~~⁵¹, wherein the shaft has at least once cavity for receiving the first and second electrode arrays when retracted.

~~55~~⁵³ (As filed) A probe as in claim ~~51~~⁴⁸ or ~~53~~⁵¹, wherein the shaft has at least one cavity for receiving the first electrode array when retracted and at least a second cavity for receiving the second electrode array when retracted.

~~56~~⁵⁴ (As filed) A probe as in claim ~~51~~⁴⁸ or ~~53~~⁵¹, further comprising:
a first rod connected to the first electrode array and slidably disposed in the shaft, wherein distal advancement of the first rod relative to the shaft causes the first electrode array to deploy distally;

a second rod connected to the second electrode array and slidably disposed in the shaft, wherein proximal retraction of the second rod relative to the shaft causes the second electrode array to deploy proximally.

~~57~~⁵⁵ (As filed) A probe as in claim ~~56~~⁵⁴, wherein the first and second rods may be deployed separately.

~~58~~⁵⁶ (As filed) A probe as in claim ~~51~~⁴⁸ or ~~53~~⁵¹, wherein the first electrode array spans a planar area in the range between 3 cm² to 20 cm² when deployed, the second electrode array spans a planar area in the range between 3 cm² and 20 cm² when deployed, and the first and second areas are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

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~~59~~⁵¹ (As filed) A probe as in claim ~~51~~⁵¹ or ~~53~~⁵¹, wherein the volume between the first electrode array when deployed and the second electrode when deployed is in the range from 30 cm³ to 150 cm³.

~~60~~⁵⁸ (As filed) A probe as in claim ~~59~~⁵⁷, wherein the volume is in the range from 50 cm³ to 70 cm³.

~~61~~⁵⁹ (As filed) A probe as in claim ~~51~~⁴⁸ or ~~53~~⁵¹, wherein the first electrode array and second electrode array are electrically isolated from each other, further comprising a first connector for connecting the first electrode array to one pole of a power supply and a second connector for connecting the second array to a second pole of a power supply.

~~62~~⁶⁰ (As filed) A probe as in claim ~~61~~⁵⁹, further comprising a first axial conductor extending proximally along the shaft from the first electrode array to a location distal to the second electrode array, said first axial conductor being electrically coupled to the first electrode array.

~~63~~⁶¹ (As filed) A probe as in claim ~~62~~⁶⁰, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.

~~64~~⁶² (As filed) A probe as in claim ~~62~~⁶⁰, further comprising a second axial conductor extending distally along the shaft from the second electrode array to a location proximal to the first axial conductor so that a gap exists between the termini of the first and second axial conductors, said second axial conductor being electrically coupled to the second electrode array.

~~65~~⁶³ (As filed) A probe as in claim ~~64~~⁶², wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial

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conductor lies closer to the first electrode array than does any portion of the second electrode array.

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~~66~~ ⁶⁴

~~64~~ ⁶²

(As filed) A probe as in claim ~~64~~, wherein the distance between the inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

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